Exhibit B

IN THE UNITED STATES DISTRICT COURT FOR THE

SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION

BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA STEVENS, individually and as personal representatives of the Estate of BETTY ERLENE KNIGHT, deceased,

Plaintiffs,

vs. No. 3:15-CV-06424

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Volume 2
Pages 122 through 400

Defendant.
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

THURSDAY, OCTOBER 4, 2018, 9:00 A.M.

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(Appearances continued next page...)

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Proceedings reported by mechanical stenography, transcript produced by computer-aided transcription.

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Also Present:

CLAUDE R. KNIGHT, Plaintiff

other information that is known that would help them prevent or avoid that bleeding risk.

Q. I want to stop for a second while this is on the screen and just ask you, do you, as part of your consulting practice, advise clients as to the types of warning instructions they need to give to doctors and patients?

A. I have, yes.

Q. And when you do that, what significance is there, if any, as to how individual state laws may apply versus FDA rules?

A. So I've worked on projects or cases where the issue is whether or not the information needs to be provided directly to a patient -- like in this case, that's my understanding here in West Virginia -- versus the information only having to be provided to the physician.

So in some projects that I work on what is most important is what is being told to the patient, and that's what this Medication Guide is. So in my view that is what is really important in this particular case, understanding what the patient was being told.

Q. Let's look at the bottom half of this page of the Medication Guide.

It says: You may have a higher risk of bleeding if you take Pradaxa and -- and it lists a bunch of things, right?

A. Yes.

Q. Can you direct Ms. Veldman to put up on the screen where in the Medication Guide it says that the 75-milligram dose was never tested on AFib patients?
A. That is not in the Medication Guide. The patient would have no way to know that.
Q. Okay. Could you tell us where we're going to find that there is no safety and effectiveness information about the 75-milligram dose?
A. That is not in there.
Q. Can you show us where there is information that one in five patients are getting too much or too little drug?
A. That is not in there.
Q. Can you point where in the Medication Guide it talks about excessive dabigatran exposure or too much Pradaxa?
A. That concept is not provided in here.
Q. Can you point to where in this label it tells us that too much Pradaxa increases your risk of bleeding?
A. It doesn't use those words.
Q. Where does it say that increasing plasma -- increasing plasma concentration increases the risk of bleeding?
A. It does not mention that relationship.
Q. Can you show the jury where in this label it says that if you're on Pradaxa, you're more likely to have a GI bleed -- strike that. Let me start again.
Tell the jury where in this Medication Guide it tells a

labeling for physicians for Pradaxa; is that right?
A. We did with -- I don't believe in the U.S. label. We did go into the European label, which was for physicians.
Q. Got it. And that's a fair clarification.
You talked about the label that doesn't apply in the United States, but you did not talk about the doctor label that would apply in the United States, right?
A. That's correct. It's my opinion the Medication Guide is what is relevant.
Q. Okay. But we can agree, because we just looked at it, that the Medication Guide also encourages patients to talk to their doctors who have access to the physician labeling, correct?
A. It does say that, that's true.
Q. Okay. And do you understand there to be --
MS. JONES: I apologize. I apologize to everyone. That's a failing of mine. I will try to do better.
Q. Do you understand there to be something that is the equivalent of the Medication Guide in Europe?
A. Yes.
Q. Have you looked at that?
A. I've seen something that was available online, yes.
Q. Did you evaluate it to determine whether you viewed it as adequate or not?
A. No. I haven't made an opinion on any specific language,

Q. And the company submitted a label, and the FDA actually sent something back striking out what the company had written?

A. Yes.

Q. You remember that?

So the idea of patients with severe renal impairment getting Pradaxa, that was not Boehringer Ingelheim's idea, correct?

A. If you're asking me the change to the 75-milligram dose, I would agree that was not theirs. But they actually -- in some of these documents they were pushing for the use of the 110 dose.

Q. Well, you understand that the FDA didn't approve the 110 dose, correct?

A. Yes, I do.

Q. And you understand I'm asking you about the 75-milligram dose, correct?

A. Yes, I do.

Q. Okay. And it is sounds like you understand that Mrs. Knight took the 75-milligram dose?

A. I do.

Q. Okay. I just wanted to get us on the same page.

And let me go back to my original question, the idea of patients with severe renal impairment getting Pradaxa, that was the FDA's idea originally, correct?

A. Getting any Pradaxa? I don't know that that was their idea. Certainly the issue of the 75-milligram dose, yes, I agree with that. That was the FDA's idea as a way to solve the problem.

Q. Okay. The FDA also viewed it as a priority that patients who had severe renal impairment would have access to Pradaxa, correct?

A. I don't know about the word priority, but certainly it was something that they were looking for. So if you read this review memo, that's what they lay out.

Q. When FDA approved the 75-milligram dose of Pradaxa, do you agree that that reflects that the FDA's judgment that the 75-milligram dose of Pradaxa was safe and effective for patients who would take it?

A. Well, I can't get in the mind, I didn't see them state it quite that way. But I would assume that they did believe it would be -- would be safe and effective to be used that way, yes, based on the fact that they made that decision for the labeling.

Q. And, in fact, if I recall your direct examination testimony, you testified that whenever the FDA approves a medicine for use, that reflects its judgment that the medicine is safe and effective for whatever the patient population is, correct?

A. Yes. That's why I answered that way. I'm assuming that

CERTIFICATION:

I, Kathy L. Swinhart, CSR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter as reported on October 4, 2018.

October 5, 2018
DATE

/s/ Kathy L. Swinhart
KATHY L. SWINHART, CSR